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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,619	09/14/2004	Giangiacomo Torri	5497	4010
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EXAMINER				
LAU, JONATHAN S				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/506,619

Applicant(s)

TORRI ET AL.

Examiner

Jonathan S. Lau

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2009 and 21 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-6, 10, 13 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-6, 10, 13 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 Apr 2009 has been entered.

This Office Action is responsive to Applicant's Amendment and Remarks, filed 21 Apr 2009, and Applicant's Amendment and Remarks, filed 20 Mar 2009, in which claims 1 and 13 are amended to change the scope and breadth of the claim and claims 7, 8, 11 and 12 are canceled.

This application is the national stage entry of PCT/EP03/02910, filed 20 Mar 2003; and claims benefit of foreign priority document EPO 02425172.0, filed 20 Mar 2002. The foreign priority document is in English.

Claims 1, 4-6, 10, 13 and 15 are pending.

Objections Withdrawn

Applicant's Amendment, filed 20 Mar 2009, with respect to objections to claim 15 has been fully considered and is persuasive, as the amended claims appear to recite the correct status of the claim.

This objection has been **withdrawn**.

Rejections Withdrawn

Applicant's Amendment, filed 20 Mar 2009, with respect to claims 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Kataoka et al. (US Patent 6,187,391, issued 13 Feb 2001, of record) as evidenced by Ward et al. (Surface Science, 1978, p257-273, of record) has been fully considered and is persuasive, as claims 11 and 12 are canceled.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 20 Mar 2009, with respect to claims 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Zara et al. (Tappi Journal, 1995, p131-134, of record) has been fully considered and is persuasive, as claims 11 and 12 are canceled.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 20 Mar 2009, with respect to claims 1, 4-8, 10-13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kataoka et al. (US Patent 6,187,391, issued 13 Feb 2001, of record) in view of Weil (US Patent

4,017,257, issued 12 Apr 1977, of record). Ward et al. (Surface Science, 1978, p257-273, of record) provides evidence of the inherency has been fully considered and is persuasive, as claims 7, 8, 11 and 12 are canceled and Kataoka et al. in view of Weil does not teach the instant method using a chemical source of free radicals wherein said chemical source is Fenton's reagent.

This rejection has been **withdrawn**.

The following are new grounds of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Amended Claims 1, 4-6, 10, 13 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites "a functionalized olefin". Claim 13 recites "an olefin containing a functional group". Claims 4-6, 10 and 15 depend from claim 1 and incorporate all limitations therein.

The specification discloses chemicals, such as glycidylmethacrylate and allylglycidylether at page 3, lines 25-30 which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 1, 4-6, 10, 13

and 15 are directed to encompass functional groups, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these functional groups meet the written description requirement of 35 USC 112, first paragraph, due to lacking chemical structural information for what they are and because chemical functional groups are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath, Inc. v. Mahurkar, 935 F.2d 935 F.2d 1555, 1563 [19 USPQ2d 1111] (Fed. Cir. 1991), makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*Vas-Cath* at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed olefins containing a functional group, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. The court of *University of California v. Eli Lilly and Co.*, 119 F.3d 1559 [43 USPQ2d 1398] (Fed.

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Cir. 1997) held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

The court of *In re Curtis*, 354 F.3d 1347 [69 USPQ2d 1274] (Fed. Cir. 2004) held that "a patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when... the evidence indicates ordinary artisans could not predict the operability ... of any other species."

Therefore, only the structurally defined chemical compounds, but not the full breadth of the claims, meet the written description requirement of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that *Vas-Cath* makes clear that the written description requirement of 35 USC 112 is severable from its enablement provision. (See *Vas-Cath* at page 1115.)

Amended Claims 1, 4-6, 10, 13 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl's 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: A process for functionalizing polysaccharides using a chemical source of free radicals, which forms stable radicals on a polysaccharide structure, wherein at least one of the formed radicals reacts with a functionalized olefin, comprising: a first step, wherein a free radical on a polysaccharide chain is formed, and a second step, wherein said radical reacts with an olefin in the absence of a radical source, wherein said chemical source is Fenton's reagent.

The state of the prior art: Zara et al. (Tappi Journal, 1995, p131-134, of record) discloses the method wherein a polysaccharide produced by the process in which the pulp cellulose fiber forms free radicals generated $\text{Fe}^{2+}/\text{H}_2\text{O}_2$, Fenton's reagent, which is followed by the addition of vinyl acetate, a functionalized olefin. See Zara et al., page 131, left column, lines 20-23 and middle column, lines 13-18 and page 134, middle column, lines 31-33 and 39-41. In the course of the reaction the $\text{Fe}^{2+}/\text{H}_2\text{O}_2$, or the radical source, is consumed. Applicant's Remarks, filed 14 Oct 2008, note that the concentration of reagents never becomes zero, although at some moment it may

become undetectable or irrelevant, that it is not zero, therefore the process is not "in absence of a radical source."

Shah et al. (Journal of Applied Polymer Science, 1994, 51, p1421-1426, cited in PTO-892) discloses the Fenton's reagent initiated graft copolymerization of acrylonitrile (AN) onto the polysaccharide sodium alginate (SA) (abstract). Shah et al. proposes a mechanism for this reaction. Shah et al. proposes that the generation of active sites directly on the polysaccharide SA by Fenton's reagent is unlikely, and the radical source OH will prefer to interact with the monomer AN, and provides that the reaction is dependent on the concentration of the monomer (page 1425, right column).

Bhattacharya et al. (Prog. Polym. Sci., 2004, 29, p767-814, cited in PTO-892), published after the instant filing date, provides evidence that In the chemical process, free radicals are produced from the initiators and transferred to the substrate to react with monomer to form the graft co-polymers, not to the polymer to react with the monomer (page 769, left column, paragraph 1 in section 2.1.1. Free-radical grafting). Bhattacharya et al. discloses that apart from the radiation technique, all chemical grafting reactions require an initiator, and its nature, concentration, solubility as well as function need to be considered (page 788, left column, paragraph 1 in section 3.4 Effect of initiator). Bhattacharya et al. discloses that the rate of grafting is dependent upon the initiator concentration as well as the monomer and the backbone polymer (page 788, left column, paragraph 2 in section 3.4 Effect of initiator).

van Dijk-Wolthuis et al. (Macromolecules, 1997, 30, p3411-3413, cited in PTO-892) provides evidence that glycidyl methacrylate can react with a polysaccharide such as dextran by a transesterification reaction (page 3412, figure 1 at top of left column) without involving the reaction of a free radical; the product of this reaction retains an ester functional group.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: While the reactivity of most chemical functionalities in abstract is relatively predictable, the sheer number of chemical structures means that one skilled in the art cannot predict all possible chemical reactions. For example, van Dijk-Wolthuis et al. provides that in a complex system an unexpected transesterification reaction may occur rather than the expected nucleophilic ring-opening of a sterically-strained epoxide (page 3412, figure 1 at top of left column). Therefore the claimed invention is unpredictable.

The Breadth of the claims: The scope of the claims is infinite. Any possible functionalized olefin could potentially be used as the olefin of the instant method.

The amount of direction or guidance presented: The specification speaks generally about the reaction of the free radical on a polysaccharide chain with an olefin in the absence of a radical source and it is suggested that the product forms carbon-carbon bonds (page 3, lines 1-5).

The presence or absence of working examples: The only working examples provided for activation by Fenton's Reagent are in example 1 disclosed at pages 7-9. In the reactions disclosed flax is reacted with Fenton's Reagent, washed with abundant

cool water, and then reacted with glycidyl methacrylate (GMA). Characterization for the flax after reaction with Fenton's Reagent and being washed with abundant cool water is done by IR, and "does not produce any change in the IR spectrum" while reaction with GMA introduces an IR absorbance typical of an ester group (page 8, lines 20-25). No data regarding formation of a carbon-carbon bond specific to the product reacted with Fenton's Reagent is provided or regarding the presence of free radicals in the flax reacted with Fenton's Reagent following washing with abundant cool water.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable art such as organic synthesis involving complex molecules. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the invention one skilled in the art would undertake a novel and extensive research program into organic synthesis to confirm that the reaction in the absence of a radical source occurs via a free radical mechanism for all olefins. All of Zara et al., Shah et al. and Bhattacharya et al. teach that the free radical reaction using a chemical source requires the presence of all of the polysaccharide backbone, the monomer, and the initiator in non-zero concentrations. As evidenced by van Dijk-Wolthuis et al. above, it is known that polysaccharides react with GMA by a mechanism that does not involve free-radicals to give a product having an ester group. Because the research would have to be exhaustive in view of the contrary teachings provided above, and because it would involve such a wide and unpredictable scope of chemical reactions, it would constitute an undue and unpredictable experimental burden.

Genentech, 108 F.3d at 1366, states that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above Applicants fail to provide information sufficient to practice the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Amended Claims 1, 4-6, 10, 13 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

Claim 1 recites "a second step, wherein said radical reacts with an olefin in the absence of a radical source". Claim 13 recites "b) reacting, in the absence of the free radical source, an olefin containing a functional group with the stable radicals on the polysaccharide". Claims 4-6, 10 and 15 depend from claim 1 and incorporate all limitations therein.

In Applicant's Remarks, filed 14 Oct 2008, regarding Zara et al. (Tappi Journal, 1995, p131-134, of record) disclosing the method wherein a polysaccharide produced by the process in which the pulp cellulose fiber forms free radicals generated $\text{Fe}^{2+}/\text{H}_2\text{O}_2$, Fenton's reagent, which is followed by the addition of vinyl acetate, a functionalized olefin, Applicant notes that the concentration of reagents never becomes zero, although at some moment it may become undetectable or irrelevant, that it is not zero, therefore the process is not "in absence of a radical source." In view of Applicant's Remarks and

the amendment to claims 1 and 13 requiring a chemical source of free radicals, the omitted steps are the critical steps necessary to remove the radical source required by the method as claimed. The specification provides, for example at page 7, lines 27, the method including the step wherein the polysaccharide is washed with abundant cool water and filtered.

Applicants are suggested to recite specific active steps in the method claims to achieve or produce the specific products in the claimed method.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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